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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,671	12/12/2003	Seth A. Foerster	END-897DIV3	6289

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WELSH & FLAXMAN LLC
2000 DUKE STREET, SUITE 100
ALEXANDRIA, VA 22314

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

MAIL DATE	DELIVERY MODE
06/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,671	FOERSTER ET AL.	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-52* is/are pending in the application.

4a) Of the above claim(s) *51 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 04/08/2010, amended claim(s) 49 is/are acknowledged. The following reiterated ground(s) of rejection is/are set forth:

Election/Restrictions

2. With respect to Applicant's assertions that claims 51 and 52 should not be withdrawn, the Examiner notes the written description to which applicant refers to specifically states that "Marker elements of many other materials and configurations may be used as well" (Specification, page 22 line 20-21), thus describing alternate marker elements as opposed to the "permanent markers" or "bioabsorbable" of the permanently implanted, outward-energy anchoring markers of Figures 1-16 (Specification, page 15 lines 7-14 and page 22 lines 7-19) and the woven biodegradable polymer marker of Figure 20 (Specification, page 23 lines 2-6).

3. Although Applicant argues that "all embodiments of the markers disclosed in this section of the specification can be either permanent or bioabsorbable. Although Applicant has constructively elected the species shown in Figure 19, this species may be either permanent or bioabsorbable", the Examiner notes Applicant mischaracterizes this disclosure and the description of the elected invention is silent with respect to this. Reiterating, the Examiner notes that the written description of the species elected by original presentation does not describe a temporal duration the plurality of small beads or pellets of radiodense calcium carbonate reside in the biopsy site nor a mention of the

physiological absorption and/or degradation thereof. The Specification merely describes the small beads of Figure 19 as being calcium carbonate and it is unclear how Applicant may maintain that a single material may be both permanent and bioabsorbable. Conversely, the non-elected species of Figures 1-16 and 20 are described in this manner (as cited above).

4. Claims 51 and 52 remain withdrawn as being directed to a non-elected invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 49-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Burton (US 3,741,198).

7. For claim 49, Burton discloses a delivery system (as best seen in Figures 1, 2, 3, and 6) for delivering biopsy marker material (ferro-fluidic marking material 28) to a biopsy site (spinal column site 10) within a patient (patient 12) (Abstract, column 3 line 63 – column 6 line 57) (as best seen in Figures 1, 3, and 6), comprising *inter alia*:

- an elongate member (puncture needle 14) (column 4 line 66 – column 5 line 17 and column 6 lines 50-57) having a distal end (the insertion/inserted end of puncture needle 14 as best seen in Figures 1, 3, and 6), a discharge port in the distal end (the open distal end of puncture needle 14 as best seen in Figures 3 and 6) and an inner

lumen (the inner lumen of puncture needle 14 as best seen in Figures 3 and 6) extending therein to and in fluid communication with the discharge port in the distal end (as best seen in Figures 3 and 6);

- a plurality of small radiodense markers (ferro-fluidic marking material 28 comprised in part of a plurality of small ferromagnetic particles) (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17) disposed within the inner lumen of the elongate member (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17) and configured to be deployed as the biopsy marker material (the radiological diagnostic marking material 28 is deployed to diagnose abnormalities including tumors, column 1 lines 8-15) (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17); and
- an ejector (the syringe positively recited in column 5 lines 12-15) which is advancable with and coupled to said elongate member (column 5 lines 12-15) and which is configured to eject the biopsy marker material from the discharge port in said distal end of said elongate member (the injection of the marker material through the puncture needle via use of the syringe as positively recited in column 5 lines 12-15) to mark a desired biopsy site for locating the biopsy site during a future examination (in one example, Burton discloses that the spinal column, e.g. the desired biopsy site, is first marked with the ferro-fluidic marking material and then the material is located in the biopsy site during subsequent X-ray examination and/or fluoroscopic examination, column 5 lines 18-29).

8. For claim 50, Burton discloses the system, wherein the plurality of small radiodense markers are beads or pellets (28) (as best seen in Figures 3 and 6) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17).

Response to Arguments

9. Applicant's arguments filed 04/08/2010 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of claim 49 under 35 U.S.C. 102(b) as being anticipated by Burton.

10. Specifically applicant argues, Burton does not disclose, teach, and/or fairly suggest the following:

a) a “biopsy site” because “The Examiner has improperly interpreted the term "biopsy site". The Examiner has interpreted this term without reference to the fact the precursor to a "biopsy site" is the performance of a biopsy. That is, and as used in the present claims in a manner understood by one of ordinary skill in the art, in order to have a biopsy site you first need to perform a biopsy. "Biopsy" is a well defined and understood term in the medical field and it is beyond a reasonable interpretation to suggest that a spinal column is a biopsy site”;

b) “a plurality of small radiodense markers deployed as a biopsy marker material disposed within the inner lumen. This structural limitation is not disclosed by Burton. Burton can't possibly disclose biopsy marker material as no biopsy is taking place in Burton. A biopsy requires the removal of tissue and a biopsy marker is used to mark

the area from which the tissue is taken, such that the area can be relocated if needed. Without a biopsy there can be no biopsy site or biopsy marker."; and

c) "the ferrofluid of Burton is not used to mark a desired site for locating the biopsy site during a future examination and thus does not function as a marker as claimed."

11. The Examiner disagrees, maintains the rejection as set forth and cited above, and in response notes the following:

12. In response to applicant's arguments that Burton fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "in order to have a biopsy site you first need to perform a biopsy", "a biopsy takes place", "removal of tissue", or "a biopsy marker is used to mark the area from which the tissue is taken") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

13. The Examiner notes that as broadly as claimed and consistent with the instant Specification, a "biopsy site" does not necessarily require a "biopsy to be performed". Although a "biopsy site" may be located where a biopsy tissue removal procedure has previously occurred, a "biopsy site" may also be a physical location on a body where a biopsy procedure is planned to take place. Furthermore, Burton is expressly concerned with performing medical diagnostic procedures based on radiological structures to determine bodily abnormalities, including at least ulcers at tumors (column 1 line 10), for further diagnosis and/or medical intervention. It is well known to those of skill in the art

that a tumor determined to be located on a spinal cord may be considered “a biopsy site” both before and/or after a "biopsy" is performed.

14. In response to Applicant’s argument, the Examiner notes the claims and limitations therein are being treated on the merits with the broadest reasonable interpretation thereof consistent with the instant Specification. The term “biopsy site” may be reasonably interpreted with its plain meaning to include “a position, location, or setting for the diagnostic study of tissue of a living body”. Burton clearly discloses the deployment and injection of the radiographic ferrofluid for radiological diagnosis of abnormalities, including for example tumors. The “desired biopsy site” is the spinal column site where the marking fluid is injected. For example, when a tumor is found this may be considered a “biopsy site” as broadly as claimed.

15. Similarly, the term “biopsy marker material” may be reasonably interpreted with its plain meaning to include “a substance of which a thing is composed that is used as an indication for the diagnostic study of tissue of a living body”. Burton clearly discloses the deployment and injection of the radiographic ferrofluid for radiological diagnosis of abnormalities, including for example biopsy-able tumors.

16. Although Burton discloses removing the ferrofluid material upon completion of the procedure, the biopsy site is first injected with the fluid to mark it and during “future” examination (i.e. during the subsequent X-ray portion of the procedure) the biopsy site is located due to the radiodense marking characteristics of the ferrofluid and biopsy site diagnosed. The term “future” may be plainly defined as “time that is to be or come hereafter”.

17. Furthermore, the Examiner notes the scope of the claimed invention does not include for example at least "obtaining a biopsy specimen" or "marking the location or margins of a lesion prior to removing the sample" (as disclosed in the instant Specification at at least page 6 lines 9-17); conversely, the scope of the claims merely recites a structure for *inter alia* ejecting with an ejector at a "biopsy site" within a patient small radiodense markers through a discharge port from a lumen of an elongate member for marking a site for locating it in the future.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am

to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736